

Exhibit

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**THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)**

ROBERT WITT,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

No. 1:20-CV-01249

[PROPOSED] STIPULATED PROTECTIVE AND CONFIDENTIALITY ORDER

Pursuant to this Stipulated Protective and Confidentiality Order (hereinafter “Protective Order”), Plaintiff Robert Witt and Defendant Novartis Pharmaceuticals Corporation (“NPC”) stipulate that:

- (1) For purposes of this Protective Order, any Party may designate as “Confidential Material” any information the Party reasonably and in good faith believes constitutes and reveals confidential trade secrets, proprietary business information, or non-public, personal, client, or customer information concerning individuals or other entities (including, but not limited to Social Security numbers, home telephone numbers and addresses, and medical information) that is contained in any document, written discovery response, testimony, or other material produced or provided by that Party or its representative(s) to the other Party, whether provided voluntarily, pursuant to formal discovery procedures, or otherwise. No information that is in the public domain (including those made public in prior litigation involving Tasigna®) or which is already known by the receiving party through proper means or which is or becomes available to a party from a source other than the party asserting confidentiality, rightfully in possession

of such information on a non-confidential basis, shall be deemed or considered to be Confidential Material under this Protective Order.

- (2) For the purposes of this Protective Order, “Confidential Material” shall also include any Protected Data, as defined hereinafter. Certain Protected Data may be subject to alternative or additional protections beyond those afforded Confidential Information, in which event the parties shall meet and confer in good faith, and, if unsuccessful, shall move the Court for appropriate relief.
- (3) “Protected Data” shall refer to any information that a party reasonably believes in good faith to be subject to federal, state or foreign data protection laws or other privacy obligations. Protected Data constitutes highly sensitive materials requiring special protection. Examples of such data protection laws include but are not limited to The Gramm-Leach-Bliley Act, 15 U.S.C. § 6801 et seq. (financial information); The Health Insurance Portability and Accountability Act and the regulations thereunder, 45 CFR Part 160 and Subparts A and E of Part 164 (medical information); Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L281/31) (European Union personal information); Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and repealing Directive 95/46/EC (General Data Protection Regulation) (L119/1) (EU personal information); Data Protection Act 1998 (c. 29) (United Kingdom personal information); the Spanish Data Protection Act 1/1999; the Belgian Law of December 8, 1992 on Privacy Protection in relation to the Processing of

Personal Data (Belgium personal information); The Federal Law on Protection of Personal Data held by Private Parties (published July 5, 2010) (Mexico personal information); and The Act on the Protection of Personal Information (Law No. 57 of 2003) (APPI) (Japan personal information); the Federal Data Protection Act of 1992 (Swiss personal information); and Personal Information Protection and Electronic Documents Act (PIPEDA), S.C. 2000, c. 5 (Canada personal information).

- (4) Any Party may designate a document as Confidential Material that the party reasonably believes qualifies as such, by stamping it “Confidential,” or “Subject to Protective Order.” All pages of any document that bears such a legend are subject to this Protective Order. The Party shall affix the stamp in such a manner so as not to obscure the text of the document. For Confidential Material produced in native format, the Producing party will indicate the designation in a manner agreed among the Parties or pursuant to the terms of an ESI protocol, if one is entered.
- (5) To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks or tapes) (“Computerized Material”) is produced by any party in such form, the producing Party may designate such materials as Confidential by marking the container that the media is produced in “Confidential.” Whenever any party to whom Computerized Material designated as Confidential is produced reduces such material to hardcopy form, that party shall mark the hardcopy form with the “Confidential” designation.
- (6) If responses to interrogatories, requests for admission, or other written responses to discovery quote, summarize, or contain Confidential Material, the Parties may designate

them as Confidential Material by marking the face of any such response with one of the legends set forth in paragraph (4) above and indicating the page and line references of the material that is to be subject to this Protective Order.

- (7) A Party may designate the transcript of any deposition in this Action or any portion thereof, including exhibits thereto, as Confidential Material by either so advising the court reporter and the Parties on the record during the taking of the deposition or within thirty (30) days after receipt of the deposition transcript by written designation served upon the Parties. If all or any portion of a deposition is designated as being subject to this Protective Order, the court reporter and any Party possessing any transcripts shall label the cover page of each transcript or copy thereof to state that the deposition includes Confidential Material, and shall label as confidential each of the pages of the transcript or exhibits that contain Confidential Material.
- (8) Any inadvertent production of any confidential or proprietary material will not result in or be construed as a waiver, in whole or in part, of (a) the producing Party's claims of confidentiality either as to the specific information inadvertently disclosed or more generally as to the subject matter of the information disclosed, or (b) the party's right to designate the material as confidential pursuant to this Protective Order. In the event that a Party inadvertently produces any Confidential Material without attaching one of the legends described in paragraph (4) above, the Party may subsequently designate the material as Confidential at any time by forwarding to the opposing Party copies of the material bearing one of the legends required by paragraph (4) and requesting that the opposing Party destroy all prior copies of the Confidential Material. Upon receipt of such a request, the opposing Party shall destroy all copies of the Confidential Material

produced inadvertently and replace them with copies bearing the appropriate confidentiality legend.

- (9) Written and oral communications between or among counsel for the Parties that refer to or discuss Confidential Material automatically shall be subject to this Protective Order.
- (10) Confidential Material shall be treated by the Parties and their counsel as being confidential and private. Any copy made of Confidential Material shall have the same status as the original. The disclosure and use of Confidential Material shall be confined to the permissible disclosures and uses set forth below. Any Confidential Material produced by the Parties shall be used (if otherwise relevant and admissible) solely for the litigation of this case, including any appeals, and for any other product liability action alleging injury as a result of use of Tassigna[®] that is pending where the court has entered a protective order offering substantially equivalent or greater protection for Confidential Material (“Permitted Actions”). A determination that a protective order in another action provides substantially equivalent or greater protection must be expressly made and agreed to by all the parties to that protective order or by the presiding court. Confidential Material shall not be used in any other legal action or proceeding or for any other purpose without further order of this Court. All other disclosure and use of Confidential Material during the pendency of this Action or after its termination is hereby prohibited.
- (11) Confidential Material may be disclosed only to the following persons and only insofar as it is reasonably necessary to the effective prosecution of the Parties’ claims and defenses:
 - (a) Parties, their representatives, in-house counsel and regular employees who are actively engaged in, or actively overseeing this case, a Permitted Action,

or involved in complying with NPC's legal obligations to provide information to the Food and Drug Administration;

- (b) Counsel of record for this case or a Permitted Action, including their associated attorneys, paralegal and secretarial personnel, and other support staff;
- (c) Counsel of record for other filed product liability actions alleging injury as a result of use of Tassigna[®], including their associated attorneys, paralegal and secretarial personnel, and other support staff, provided that a protective order providing substantially equivalent or greater protection for NPC's Confidential Information has been entered by the court in the other filed action;
- (d) Experts and consultants (including their employees) who are retained by a Party to assist in the litigation of this case or a Permitted Action;
- (e) Third-party contractors and their employees who are retained by one or more Parties to provide litigation-support or copy services in this case;
- (f) Witnesses or prospective witnesses in this case or a Permitted Action;
- (g) Court reporters and other persons involved in recording deposition testimony in this case or a Permitted Action;
- (h) Court personnel of the United States District Court for the District of Maryland, or, if on appeal, of The United States Court of Appeals for the Fourth Circuit, or a Permitted Action, or if on appeal, a court with appellate jurisdiction;
- (i) Jurors in this case or a Permitted Action; and

- (j) The Food and Drug Administration, to the extent NPC is required to disclose any Confidential Material by law.

Counsel for each Party disclosing Confidential Material in accordance with this paragraph shall (i) advise each person to whom such disclosure is made (except Court personnel, jurors, and the Food and Drug Administration) of the terms of this Protective Order and of the obligation of each such person to comply with those terms and (ii) provide a copy of this Protective Order to each such person. Prior to the disclosure of any Confidential Information to any person identified in subparagraphs c, d, e, f, and g above, such person shall sign an Acknowledgment, in the form attached hereto as Exhibit 1, acknowledging that he or she has read this Protective Order and shall abide by its terms. Counsel shall maintain a list of persons to whom confidential materials are disclosed (excluding jurors, Court personnel, and the Food and Drug Administration). Upon learning of any disclosure of Confidential Material to any person not authorized by this paragraph to receive Confidential Material, the Party who so learns shall immediately (i) inform in writing the Party from which the Confidential Material was originally received of such disclosure, including to whom the material was disclosed, and (ii) take all necessary steps to retrieve as soon as possible each and every copy of all Confidential Material from the unauthorized person and any person to whom the unauthorized person disclosed the Confidential Material.

- (12) Documents bearing confidentiality designations shall not be used as exhibits at trial. The Parties shall redact confidentiality designations from any documents to be used as exhibits at trial and do so in a manner that ensures the redaction of the confidentiality designation is not visible. Alternatively, before trial, and upon request, the producing

Party shall provide copies of such documents free of any confidentiality designation for use at trial. Such documents shall be used only for trial purposes and shall be destroyed or returned, along with any and all copies made, to the producing Party after this case is finally determined as to the Party to whom the documents were produced.

- (13) Each Party agrees that in the event it is served by a non-party with a subpoena or request for production of Confidential Material originally received from another Party, it will give sufficient notice to allow that Party a reasonable opportunity to intervene to oppose such production. The notice shall include a description of the material sought, the date and location for compliance with the subpoena or request, the identity of the requester of the Confidential Material, the docket number of the matter where requested and all other information reasonably necessary to intervene and oppose such production.
- (14) Personally identifiable information that a Party has designated as Protected Data based on its reasonable and good faith belief that the information is subject to federal, state or foreign data protection laws, data privacy laws, or other privacy obligations, or any of the information contained therein, shall be handled by the receiving Party with highest care, including but not limited to the procedures that they would employ to protect their own personally identifiable information; and the documents produced shall be stored and secured in a manner designed to prevent access to persons other than the above-listed permitted individuals, and that all such information stored in electronic form shall be password protected.
- (15) Should any Party to whom Confidential Material is disclosed object to the designation of that material as proprietary, confidential, or otherwise protected, it shall make a good-faith effort to resolve the dispute informally with the disclosing Party. Except where

good cause is shown, all objections to the designation of documents as Confidential Material must be interposed in writing no later than thirty (30) days after the close of merits discovery (or within 120 days after production, if the production occurs after the close of merits discovery), or such objections shall be deemed waived. Should the Parties be unable to resolve the dispute, the Party opposing the inclusion of such material under this Protective Order, within a reasonable time, may apply in writing to the Court for a ruling that the information should not be entitled to protection under this Protective Order. The Party designating the material as confidential shall have the burden of proving that said material is subject to protection. Until such time as the Court rules on the motion, the material that is the subject of the dispute shall continue to be subject to this Protective Order.

(16) CLAWBACK OF PRIVILEGED MATERIAL

(16.1) The clawback of privileged material and the determination of whether a production was inadvertent will be governed by the Rule 502(d) Order entered in this case.

(16.2) The inadvertent production by any Party in the course of discovery in these proceedings of a document subject to a claim of privilege, work product, or other applicable privilege or protection, will not result in a waiver of any of the foregoing protections, whether in these or any other proceedings, for the produced document or any other withheld document covering the same or similar subject matter, pursuant to Federal Rule of Evidence 502(d).

(16.3) If a Party believes that it has inadvertently produced any such privileged or protected materials, it shall promptly notify in writing the receiving Parties of the claim of privilege. Upon such notice, the receiving Parties shall promptly: (1) use

commercially reasonable efforts to locate and destroy all copies of the material in their possession, custody or control, including material stored in any litigation-support or other database and all notes or other work product reflecting the content of the material, and notify the producing Party that they have done so; and (2) take all commercially reasonable steps to retrieve and destroy all copies of the inadvertently produced material or documents from other persons, if any, to whom such documents or materials were distributed. Receiving counsel shall certify in writing to the producing party's counsel that any notes or other work product reflecting the inadvertently disclosed document's contents have been destroyed by counsel, the receiving party, and any experts or others in their employment. If, however, a receiving Party disputes the producing Party's assertion of privilege, the receiving Party shall notify the producing Party in writing within 15 business days of receiving the producing Party's notice. Within 30 business days of receiving such notice of dispute, the Parties shall meet and confer to resolve the dispute. If they are unable to resolve their dispute, the Party seeking to invoke privilege may submit the issue to the Court. In any such submission, the disputed documents or material shall be filed, if at all, under seal.

- (17) A Party wishing to file a document that has been designated as confidential in support of a motion or other filing with the Court ("Filing Party") shall provide reasonable notice to the Party who has made the confidential designation ("Designating Party") of the document(s) it intends to file, so as to give the Designating Party adequate opportunity to seek leave to file the document under seal. Seven (7) days is presumptively reasonable notice of an intent to file a document that has been designated as confidential under the

terms of this Protective Order, if fewer than twenty (20) documents are at issue. In the event that the Designating Party wishes to request that the document be filed under seal and a Court ruling on sealing is not obtained prior to the filing date, the Filing Party will abstain from publicly filing the document until the Court rules as to whether the document may be filed under seal. To the extent permitted by the Court, the Filing Party may provisionally file the document under seal pending resolution of the Designating Party's sealing request. If a motion to file under seal is denied by the Court, this Protective Order shall not bar the Filing Party from filing the documents in support of a motion or other filing.

- (18) Any Party who wishes to file a document under seal must comply with the applicable federal and local rules, and Electronic Case Filing Civil Procedures of the District of Maryland. *See, e.g.*, D. Md. L.R. 105; D. Md. Electronic Case Filing Civil Procedures, Sealed Civil Documents, <https://www.mdd.uscourts.gov/content/sealed-civil-documents>.
- (19) The recipient of any Confidential Material that is provided under this Protective Order shall maintain such information in a reasonably secure and safe manner that ensures that access is limited to the persons authorized under this Protective Order, and shall further exercise the same standard of due care with respect to the storage, custody, use, and/or dissemination of such information as is exercised by the recipient with respect to its own proprietary information.
- (20) Data Security: Any person in possession of Confidential Material shall maintain a written information security program that includes reasonable administrative, technical, and physical safeguards designed to protect the security and confidentiality of such Confidential Material, protect against any reasonably anticipated threats or hazards to the

security of such Confidential Material, and protect against unauthorized access to Confidential Material. To the extent a party or person does not have an information security program, they may comply with this provision by having the Confidential Material managed by and/or stored with eDiscovery vendors or claims administrators that maintain such an information security program. If a receiving party or authorized recipient discovers any loss of Confidential Material or a breach of security, including any actual or suspected unauthorized access, relating to another party's Confidential Material, the receiving party or authorized recipient shall: (1) promptly provide written notice to disclosing Party of such breach; (2) investigate and make reasonable efforts to remediate the effects of the breach, and provide disclosing Party with assurances reasonably satisfactory to disclosing Party that such breach shall not recur; and (3) provide sufficient information about the breach that the disclosing Party can reasonably ascertain the size and scope of the breach. The receiving party or authorized recipient agrees to cooperate with the producing Party or law enforcement in investigating any such security incident. In any event, the receiving party or authorized recipient shall promptly take all necessary and appropriate corrective action to terminate the unauthorized access.

- (21) This Protective Order shall not prevent the Parties from using or disclosing their own documents and other materials in any manner, notwithstanding their designation as Confidential Material subject to this Protective Order. The use or disclosure by a Party of its own documents or materials shall not terminate, waive or otherwise diminish in any way the status of such documents or materials as Confidential Materials subject to this

Protective Order. This provision does not apply if a party publicly uses or discloses documents or materials that the Party previously designated as Confidential Material.

- (22) Upon written request of the disclosing Party after the final determination, including any appeals related thereto, all Confidential Material of an opposing Party should be returned or destroyed. Within thirty (30) days after the date of the written request, all attorneys in possession of Confidential Material shall return all Confidential Material to the disclosing Party or, alternatively, shall immediately destroy all such material. This provision does not apply to materials that Defendant is required to maintain and report pursuant to statutory and regulatory obligations, such as adverse event information submitted to the FDA. All counsel of record shall, within forty-five days of the written request, certify that all Confidential Material, including any such material disclosed to any other entity, has been returned or destroyed. The sole exception to the requirements described above is that information that has been incorporated into attorney work product or other privileged documents need not be returned or destroyed. Such information shall be retained by the person to whom the information was produced, and shall be treated as Confidential Material in accordance with this Protective Order.
- (23) This Protective Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Protective Order imply that material designated (or not designated) as Confidential Material under the terms of this Protective Order is properly discoverable, relevant or admissible in this or any other litigation.
- (24) Each Party shall retain all rights and remedies available to it under the law for the enforcement of Protective Order against anyone who violates it.

- (25) The restrictions of Protective Order shall continue to apply after this action is finally determined and the Court shall retain jurisdiction for all purposes in connection therewith. All persons receiving or given access to Confidential Material in accordance with the terms of this Protective Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Protective Order and remedying any violations thereof.

Stipulated to by:

Plaintiff

Craig M. Silverman

Date

Richard Elias

Date

Defendant

Robert E. Johnston

Date

EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)**

ROBERT WITT,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

No. 1:20-CV-01249

**ACKNOWLEDGEMENT AND AGREEMENT TO BE
BOUND BY PROTECTIVE AND CONFIDENTIALITY ORDER**

The undersigned agrees and declares under penalty of perjury the following:

I hereby attest that information or documents designated confidential are provided to me subject to the Protective and Confidentiality Order (hereinafter "Protective Order") in the above-captioned case. I have read this Protective Order in its entirety and agree to comply with and to be bound by all the terms of this Protective Order. I understand that my execution of this Acknowledgment, indicating my agreement to be bound by this Protective Order, is a prerequisite to my review of any information or documents designated as confidential pursuant to the Protective Order. I also understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Protective Order except in strict compliance with the provisions of this Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the District of Maryland for the purpose of enforcing the terms of this Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

Date: _____

City and State where sworn and signed: _____

Printed Name: _____

Signature: _____